SUMMARY: The Food and Drug Administration (FDA) announces its approval of the application for premarket approval under the Medical Device Amendments of 1976 of the Model 5992 Byrel Atrioventricular Pacemaker, sponsored by Medtronic, Inc., Minneapolis, MN. After reviewing the Cardiovascular Device Classification Panel's recommendations, FDA notified the sponsor that the application was approved because the device had been shown to be safe and effective for use as recommended in the submitted labeling.

DATE: Petitions for administrative review by September 4, 1979.

ADDRESS: Petitions for administrative review may be sent to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Keith Lusted, Bureau of Medical Devices (HFK–402), Department of Health, Education, and Welfare, Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION: The sponsor, Medtronic, Inc., Minneapolis, MN 55940, submitted an application for premarket approval of the Model 5992 Byrel Atrioventricular Pacemaker to FDA on November 21, 1978. The application was reviewed by the Cardiovascular Device Classification Panel, an FDA advisory committee, which recommended approval of the application. On March 27, 1979, FDA approved the application by a letter to the sponsor from the Director of the Bureau of Medical Devices.

FDA has concurred in the Cardiovascular Device Classification Panel's recommendation to approve the premarket approval application subject to the following condition:

In one year the company shall provide the FDA with post-marketing clinical followup registry data for all of these pacemakers.

A summary of the information on which FDA's approval is based is available upon request from the Hearing Clerk (address above). Requests should be identified with the name of the device and the Hearing Clerk docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of FDA's decision to approve this application. A petitoner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and FDA's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration of FDA action under § 10.33(b) (21 CFR 10.33(b)). A petition must designate the form of review that the petitioner requests (hearing or independent advisory committee) and must be accompanied by supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing any petition, FDA will decide whether to grant or deny the petition and publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will indicate the issues to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before September 4, 1979, file with the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, four copies of each petition and supporting data and information, identified with the name of the device and the Hearing Clerk docket number found in brackets in the heading of this document. Received petitions may be seen in the above-named office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 27, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-23931 Filed 8-2-79; 8:45 am]

BILLING CODE 4110-03-M

[FDA-225-79-0011]

National Toxicology Program; Memorandum of Understanding With National Toxicology Program

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has executed a memorandum of understanding (MOU) with the National Toxicology Program. The purpose of the memorandum is to delineate responsibilities for conducting an evaluation of toxicological problems.

DATE: The agreement became effective May 7, 1979.

FOR FURTHER INFORMATION CONTACT: Gary Dykstra, Regulatory Operations Section (HFC–22), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md 20857, 301–443–3470.

SUPPLEMENTARY INFORMATION: Pursuant to the notice published in the Federal Register of the October 3, 1974 (39 FR 35697) stating that future memoranda of understanding and agreements between FDA and others would be published in the Federal Register, the Commissioner of Food and Drugs is issuing the following memorandum of understanding:

Memorandum of Understanding Between the National Toxicology Program and the Food and Drug Administration

I. Purpose

The purpose of this memorandum of understanding is to delineate the responsibilities of the National Center for Toxicological Research, Food and Drug Administration, in conducting the evaluation of toxicological problems as a part of the National Toxicology Program (NTP).

II. Background

On November 15, 1978, the Secretary of HEW announced a new initiative: the National Toxicology Program. Resources totaling $41 million from four agencies were dedicated to the new program. The participating agencies are the Food and Drug Administration, National Cancer Institute, National Institute for Environmental Health Sciences, and the National Institute for Occupational Safety and Health. The chief goal of the National Toxicology Program is to strengthen the numerous Departmental activities related to the development and validation of new and improved toxicological test methods. FDA's commitment to the new program is represented by resources dedicated by the National Center for Toxicological research (NCTR). This resource commitment totals $7 million. Therefore, it is deemed appropriate to specify the nature of the NCTR commitment to the National Toxicology Program via a memorandum of understanding.

III. Substance of Agreement

The following NCTR units and projects with associated costs represent the FDA/NCTR commitment to the National Toxicology Program:

1. *Chemical Selection and Intelligence*—The office of Scientific Intelligence, directed by Dr Larry Fishbein, will direct its efforts to the gathering and evaluation of toxicological data concerning compounds of interest to the National Toxicology Program. In addition, this staff will assist in the development of protocols used by the Division of Chemical Toxicology to conduct experimental studies on compounds selected for study by the NTP. Dr. Fishbein will function as the liaison officer with NTP. Costs for this effort:

a. 10 man years ($1,000,000),

b. $400,000 for library services contractrual effort.

2. *Toxicology Data Management Systems (TDMS)*—The NTP requires the use of an efficient and cost effective data management and analysis system. NCTR has assembled, under TDMS, the necessary expertise, hardware, and software to meet the needs of NTP. Mr. Al Konvicka will function as the TDMS liaison officer with NTP. Therefore, to meet existing needs and to develop the system to accommodate the special requirements of NTP, the NCTR will allocate the following resources:

a. 7 man years ($700,000),

b. $1,500,000 for contractual efforts.

3. *Teratology Studies*—Guidelines for testing in reproduction and teratology have not directly or specifically addressed postnatal functional alterations following prenatal exposures. NCTR proposes to attack the problem of standardization and validation of test procedures in a collaborative fashion using scientists from government, academia, and industry. Several behavioral test methods which appear to have the greatest potential utility as screening tests will be selected; standardized protocols will be written, and contracts to perform the tests will be awarded. After completion of the three year project, the data will be presented at a conference and recommendations will be made concerning the incorporation of behavioral teratology testing guidelines.

Current teratologic methods do provide meaningful data about the teratogenic potential of chemicals. To ensure that all scientific data gathered during these evaluations are utilized effectively, a comprehensive literature review and evaluation of chemicals for which there is definitive human and animal teratology information will be performed.

In addition, existing laboratory data bases will be examined to determine the range of dose parameters that indicate linearity of response and permit the development or identification of appropriate biomathematical procedures for low dose risk estimation. Dr. Joe Holson will serve as liaison officer with NTP for each of these activities. The following resources will be committed:

a. 4 man years ($400,000),

b. $300,000 for contractual efforts.

4. *Heritable Translocation Assay*—There are currently only two in vivo mammalian assays which can be employed to assess true mutagenic damage: The mouse specific locus test and the heritable translocation assay. The end-point measured by the heritable translocation test is transmitted to live progeny and provides unequivocal evidence of true mutational damage. This property, chromosome breakage and reciprocal exchange of the borken parts, together with the low spontaneous occurrence of translocations allow for a definitive evaluation of mutagenicity which is a necessity in making regulatory decisions.

The NCTR will develop a planned approach to conducting a collaborative study to determine the feasibility of using the heritable translocation assay as a means of approaching risk assessment for genetic events. Dr. Jack Bishop will function as the liaison officer with NTP. The following resources will be dedicated to this effort:

a. 5 man years ($500,000),

b. $100,000 for contractual efforts.

5. *Compound Evaluation*—The unique capabilities of NCTR in conducting toxicological evaluations will be brought to bear on chemicals requiring more than the chronic bioassay for carcinogenesis. The Divison of Chemical Toxicology at NCTR, in conjunction with other operational units at NCTR, will have primary responsibility for conducting toxicological evaluations of compounds selected for study in the National Toxicology Program. Dr. Neil Littlefield will function as the liaison officer with NTP. The following compounds are among those to be studied initially at NCTR: Gentian violet, rotenone, sulfamethazine, caffeine, cinnamaldehyde, butyl nitrite, capsaican, cineol, ethyl benzene, trimellitic anhydride, and gluteraldehyde, chloramine, and 2,3,7,8-tetrachloro dibenzodioxin. The following resources will be dedicated to this effort: 21 man years ($2,100,000).

The proceeding declaration of resources represents 47 man years, $4,700,000 in salaries and overhead, and $2,300,000 in contractual costs as shown in the following table:

Cost Summary

Commitment	Man years	Salaries plus overhead	Additional costs contractual
Chemical Selection & Intelligence	10	$1,000,000	$400,000
Toxicology Date Management Systems	7	700,000	1,500,000
Teratology Studies	4	400,000	300,000
Heritable Translocation Assay	5	500,000	100,000
Compound Evaluation	21	2,100,000	0
Subtotals	47	4,700,000	2,300,000
Grand Total			7,000,000

IV. Name and Addresses of Participating Activity

Department of Health, Education, and Welfare, Public Health Service, National Toxicology Program, P.O. Box 12233, Research Triangle Park, North Carolina 27709.

Department of Health, Education, and Welfare, Public Health Service, Food and Drug Administration, 5600 Fishers Lane, Rockville, Maryland 20857.

V. Liaison Officers

Dr. John Moore, Deputy Director, National Institutes of Health, National Toxicology Program, Research Triangle Park, North Carolina 27709 (919-541-3267).

Dr. Jeffrey A. Staffa, Associate Director for Research Operations & Planning, National Center for Toxicological Research, Food and Drug Administration, 5600 Fishers Lane, Room 9-39, Rockville, Maryland 20857 (301-443-3155).

VI. Period of Agreement

This agreement, when accepted by both parties, will have an effective period of performance from date of signature until September 30, 1979, and may be modified by mutual consent by both parties or may be terminated by either party upon a 45-day advance notice to the other. The resources committed to the NTP shall be established by amendment or a new agreement at the beginning of each fiscal year.

Dated: May 23, 1979.

Approved and Accepted for the National Toxicology Program.

David P. Rall,

Director NTP.

Dated: May 7, 1979.

Approved and Accepted for the Food and Drug Administration.

Dorald Kennedy,

Commissioner of Food and Drugs.

Effective date. This Memorandum of Understanding became effective May 7, 1979.

Dated: July 30, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-23932 Filed 8-2-79; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 78P-0403]

Bacitracin Zinc-Polymyxin-Neomycin Topical Ointment; Exemption From Certification

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces approval of Dow Chemical U.S.A.'s petition requesting that its drug product Neo-Polycin, topical antibiotic ointment (bacitracin zinc-neomycin sulfate-